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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SMITH, RUTH S

ART UNIT

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3737

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/781,984	Applicant(s) MANDRUSOV ET AL.	
	Examiner Ruth S. Smith	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-14,32 and 38-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-14,32 and 38-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 24, 2011 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1,3-14,32,44-48,55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, it is unclear as to whether the lumen set forth on line 5 differs from the lumen set forth on line 3. In claim 1, line 8, it is unclear as to which lumen is being referred to. In claim 7, if the needle is not part of the delivery device, it is unclear as to how positioning the delivery device results in positioning a port of the needle.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States

only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 3, 5-9, 12, 14, 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Makower et al (6,602,241). The claims are directly readable on Makower et al which disclose a method of delivering substances to extravascular treatment sites. The method includes advancing a catheter into a blood vessel and imaging 360 degrees about the vessel wall to locate a treatment site using a phased array transducer. The imaging is used to guide the positioning and rotational orientation of the catheter within the vasculature to ensure proper placement of the penetrator to the target site. Makower discloses that the desired treatment site can include a periadventital area outside but close to the vessel wall (col 3, lines 1-9). Imaging 360 degrees about the vessel wall using a phased array positioned at the catheter tip will inherently include imaging a thickness of at least a portion of the vessel wall as evidenced by Jenkins (5,109,859), see figures 1A,B. The image includes a penetrator path indication that indicates the path that will be followed by the penetrator when it is advanced to the target site. The path indication is interpreted as identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging. The catheter is then advanced through the vessel wall to deliver a treatment agent to a target site. The treatment agent can include a sustained release composition in a carrier (col 16, lines 50-67, col 17, lines 1-5). The treatment agent can include an inflammation-inducing agent directed to a specific binding site to stimulate angiogenesis (col 1-2). The device is advanced through the vessel wall to an extravascular treatment site and therefore would provide the treatment site as set forth in claims 5,6. The use of Makower et al would include treatment sites as set forth in claims 7,8. The catheter includes a flexible needle device for both penetrating the vessel wall and for delivering treatment material. The device is considered be a "ribbon member deflector" which deflects the tip of the needle.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4,32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Selmon et al (6,514,217). Makower et al disclose the invention as discussed above but fails to disclose the use of optical imaging such as OCT. Makower et al disclose that other types of imaging devices can be used instead of ultrasound. The use of both ultrasound and OCT are well known in the art for imaging blood vessels as seen for example in Selmon et al. It would have been obvious to one skilled in the art to have modified Makower et al such that the imaging modality used is OCT. Such a modification merely involves the substitution of one known type of imaging modality for another.

Claims 7, 8, 10-13, 46, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al. Makower et al disclose the invention as discussed above but fails to specifically disclose the treatment sites as set forth in claims 7, 8 or the agents/carriers as set forth in claims 10-13, 46, 47. The use of the device for any known treatment site in the body would have been obvious to one skilled in the art given the disclosed agents provided by Makower et al. With respect to claim 10, in the absence of any showing of criticality, the specific size of the carrier used would have

been an obvious design choice of known equivalents in the art. With respect to claims 11-13, 46, 47, in the absence of any showing of criticality, the specific type of drug delivered would have been an obvious selection of known drugs and their uses based upon the desired patient treatment.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Segal (2002/0131974). Makower et al disclose the invention as discussed above but fails to specifically disclose the use of an opsonin-inhibitor. The use of an opsonin-inhibitor is known in order to modulate the response to carriers put into a subject for treatment purposes. It would have been obvious to one skilled in the art to have modified Makower et al such that the carrier includes an opsonin-inhibitor as is a well known expedient in the art of drug delivery.

Claims 12, 13, 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Slepian et al (5,749,915). Makower et al disclose the invention as discussed above but fails to specifically disclose the agents set forth in claims 12, 13, 47 above. The use of materials such as polycaprolactone and polyurethane for treatments involving blood vessels are known as taught by Slepian et al and the use of such known materials would have been obvious. The materials can be incorporated into carriers for delivery such as nanoparticles or liposomes and can include other particles such as metallic particles. The materials can be inflammation inducing and are heated when introduced into the body. It would have been obvious to one skilled in the art to have modified Makower et al such that materials, such as polycaprolactone and polyurethane in carriers such as metallic particles are used to further treat the vessels as is a well known expedient in the art.

Claims 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al in view of Yock (5,676,151) or Ouchi (6,338,717). Makower et al disclose the invention as discussed above but fails to specifically disclose the use of a balloon

through which the imaging occurs. It is a well known expedient in the art to provide a balloon at the end of a device paced in the body in order to the device to be fixed at a desired location. Examples of medical devices which include a balloon at the tip of the device and an imaging means which images through a transparent material of the balloon is shown in Yock and Ouchi. It would have been obvious to one skilled in the art to have modified Makower et al such that the catheter includes a balloon through which the imaging occurs as such is a well known expedient for positioning a catheter in the body for diagnosis or treatment.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al ('241) in view of Myers et al (5,725,551). Makower et al disclose a method of delivering substances to extravascular treatment sites. The method includes advancing a catheter into a blood vessel and imaging 360 degrees about the vessel wall to locate a treatment site. The image includes a penetrator path indication that indicates the path that will be followed by the penetrator when it is advanced to the target site. The path indication is interpreted as identifying a treatment site beyond an external elastic lamina of the blood vessel based on the imaging. The catheter is then advanced through the vessel wall to deliver a treatment agent to a target site. The imaging transducer is located in a lumen of the catheter and can include an ultrasound imaging device. Makower et al fail to disclose measuring the thickness of the vessel wall imaged. It is well known in the art that ultrasound can be used to determine vessel wall thickness. An example of such is seen in Myers et al. It would have been obvious to one skilled in the art to have used the ultrasound imaging device of Makower et al to further measure the thickness of the vessel wall and use the thickness measurement in addition to the images to further ascertain the path to the treatment site.

Claims 38-43, 51-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al (6,602,241) in view of Makower et al (6,190,353). Makower et al ('241) disclose a method of delivering substances to extravascular treatment sites. The method includes advancing a catheter into a blood vessel and imaging 360 degrees

about the vessel wall to locate a treatment site. The imaging transducer is located in a lumen of the catheter and can include an ultrasound imaging device. Imaging 360 degrees about the vessel wall using a phased array positioned at the catheter tip will inherently include imaging a thickness of at least a portion of the vessel wall as evidenced by Jenkins (5,109,859), see figures 1A,B. The catheter is then advanced through the vessel wall to deliver a treatment agent to a target site. The treatment agent can include a sustained release composition in a carrier (col 16, lines 50-67, col 17, lines 1-5). The treatment agent can include an inflammation-inducing agent directed to a specific binding site to stimulate angiogenesis (col 1-2). The catheter includes a flexible needle device for penetrating the vessel wall and for delivering treatment material to the target site. The device is considered be a "ribbon member deflector" which deflects the tip of the needle. Makower et al et al ('241) fails to disclose the use of a balloon to direct the distal portion of the delivery device toward the wall of the blood vessel. Makower et al ('353) disclose a method of delivering substances to extravascular treatment sites. The method include the use of a balloon positioned around the catheter device to ensure that it remains in place during operation of the device. The use of such balloons on intravascular catheters is a well known expedient in the art. It would have been obvious to one skilled in the art to have modified Makower et al ('241) such that the distal portion of the delivery device is directed toward the wall of the blood vessel in order to maintain its proper position during the procedure as is well known in the art. Makower et al ('241) fails to specifically disclose the agents/carriers as set forth in claims 41-43, 51, 52. In the absence of any showing of criticality, the specific type of drug delivered would have been an obvious selection based upon the desired patient treatment.

Claims 41-43,52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al('241) in view of Makower et al ('353) as applied to claim 38 above and further in view of Slepian et al (5,749,915). Makower et al ('241) disclose the invention as discussed above but fails to specifically disclose the agents set forth in the claims. The use of materials such as polycaprolactone and polyurethane for treatments

involving blood vessels are known as taught by Slepian et al and the use of such known materials would have been obvious. The materials can be incorporated into carriers for delivery such as nanoparticles or liposomes and can include other particles such as metallic particles. The materials can be inflammation inducing and are heated when introduced into the body. It would have been obvious to one skilled in the art to have further modified Makower et al such that materials, such as polycaprolactone and polyurethane in carriers such as metallic particles are used to further treat the vessels as is a well known expedient in the art.

Claims 49,50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al ('241) in view of Makower et al ('353) as applied to claim 38 above and further in view of Yock (5,676,151) or Ouchi (6,338,717). Makower et al ('241) fails to specifically disclose the use of a balloon through which the imaging occurs. It is a well known expedient in the art to provide a balloon at the end of a device paced in the body in order to the device to be fixed at a desired location. Examples of medical devices which include a balloon at the tip of the device and an imaging means which images through a transparent material of the balloon is shown in Yock and Ouchi. It would have been obvious to one skilled in the art to have further modified Makower et al such that the catheter includes a balloon through which the imaging occurs as such is a well known expedient for positioning a catheter in the body for diagnosis or treatment.

Claim 54 is rejected under 35 U.S.C. 103(a) as being unpatentable over Makower et al ('241) in view of Makower et al ('353) as applied to claim 38 above and further in view of Selmon et al (6,514,217). Makower et al ('241) disclose that other types of imaging devices can be used instead of ultrasound. The use of both ultrasound and OCT are well known in the art for imaging blood vessels as seen for example in Selmon et al. It would have been obvious to one skilled in the art to have further modified Makower et al such that the imaging modality used is OCT. Such a modification merely involves the substitution of one known type of imaging modality for another.

Response to Arguments

Applicant's arguments filed January 24, 2011 have been fully considered but they are not persuasive. Applicant states that Makower fails to disclose imaging a wall thickness and identifying a treatment site based on the imaging. The Examiner disagrees. The imaging transducer in Makower is located in a lumen of the catheter and can include an ultrasound phased array imaging device. Imaging 360 degrees about the vessel wall using a phased array positioned at the catheter tip will inherently include imaging a thickness of at least a portion of the vessel wall as evidenced by Jenkins (5,109,859). These images are used to determine where the penetrator will be inserted. Therefore the treatment site is identified based on the images acquired. Makower discloses that the desired treatment site can include a periadventital area outside but close to the vessel. One using the method of Makower would understand that in order to properly place the device at such a location, the method would include determining the location of the site from the acquired images. Makower further discloses that a penetrator and a separate delivery catheter can be used or the penetrator could also be used to deliver the treatment material (col 7, lines 5-31).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S. Smith whose telephone number is (571)272-4745. The examiner can normally be reached on M-F 7:30 AM-4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

RSS